FDA-Industry GDUFA Reauthorization Meeting
December 2, 2015, 10:00 am - 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss current FDA facility review and operations.

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Ashley Boam	CDER	Kiran Krishnan	GPhA (Apotex)
Mary Beth Clarke	CDER	Alan Nicholls	BPTF
Keith Flanagan	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Brian Hasselbalch	CDER	Nawel Rojkjaer	GPhA (Mylan)
Michael Jones	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA (Catalent)
Edward Sherwood	CDER	Elizabeth Stampa	EFCG (Medichem)
Martin Shimer	CDER	Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Nicholas Alexander, Carter Beach, Heather Brown, Derek Griffing, Martha Nguyen, Katie Stronati, Trang Tran, Lucie Yang

Industry Supporting Staff
Lisa Tan (GPhA), Mark Hendrickson (GPhA)

Discussion
Meeting participants discussed drug quality facility evaluations, including preapproval and postmarket inspections, and FDA described the considerations for each type of evaluation. Additionally, FDA explained the foreign inspection coordination and clearance process and how the facility evaluation affects application review timelines. Industry highlighted the importance of transparency with respect to facility evaluation information.

Next Meeting
The next negotiation meeting is planned for Wednesday, December 16, 2015.